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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,176	02/01/2001	Michael J. Ackerman	07039-234001	7283
26191	7590	02/24/2004		
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402				
			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER 16

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/775,176

Applicant(s)

ACKERMAN ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-15, 21-27 is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/24/03 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunig (4622980).

Claims 1 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Ekwall (6016443).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ekwall (or 103 (a) for Kunig). Ekwall states that a conventional cardiac electrode system is used which would include a V4 lead.

In the alternative, Ekwall (or Kunig) discloses the claimed invention except for obtaining the ECG with the V4 lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECG system as taught by Ekwall (or Kunig), with the use of an electrode at the left 5<sup>th</sup> rib interspace (the V4 lead) since it was known in the art that ECG systems use the V4 lead as a conventional lead to easily receive the ECG signals from the heart.

Claims 2-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekwall (or Kunig) in view of Ben-Haim (6285898).

Ekwall (or Kunig) discloses the claimed invention except for chemically stressing the patient to a heart rate over 100 bpm. Ben-Haim teaches that it is known to chemically stress the

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patient with dobutamine to provide a stress/exercise test resulting in a heart rate above 100 bpm for indicating cardiac health when an exercise stress test is not possible. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac method and system as taught by Ekwall (or Kunig), with the chemical stressing of the patient resulting in a heart rate above 100 bpm as taught by Ben-Haim, since such a modification would provide a cardiac method and system using chemical stressing (dobutamine) of the patient to provide a stress/exercise test resulting in a heart rate above 100 bpm for indicating cardiac health when an exercise stress test is not possible.

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac health monitor with a chemical stress test as taught by Ekwall (or Kunig) in view of Ben-Haim, with the stress/exercise test being used to produce a heart rate above 100 bpm since it was known in the art that cardiac monitors with stress/exercise tests use the test to produce a heart rate above 100 bpm to map and determine the condition of the heart at a rate indicative of a patient exercising or under stress.

***Allowable Subject Matter***

Claims 12-15 and 21-27 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The subject matter of the independent claims could either not be found or was not suggested in the prior art. The subject matter not found was the method and system detecting non-alternating fluctuations in T-wave morphology for isochronic points between consecutive T-waves and determining a T-wave lability index as a function of the non-alternating fluctuations, in combination with the other elements in the claims. The T-wave lability index being described in

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the specification for the fluctuations for isochronic points as being a maximal value of root mean square differences for the isochronic points.

### ***Response to Arguments***

Applicant's arguments filed 9/30/03 have been fully considered but they are not persuasive. The argument that Kunig or Ekwall does not detect non-alternating fluctuations in T wave morphology for isochronic points between consecutive T-waves is not persuasive. Any sensor/electrode and/or processing system that detects the ECG signal from the heart will detect non-alternating fluctuations in T wave morphology for isochronic points between consecutive T-waves since the sensor/electrode and/or processing system detects all points in the ECG cycle. Although, claims 12-15 and 21-27 have been indicated as allowable since they contain a further step/structure to processing the detection of the fluctuations in a particular way.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

• If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko  
Primary Examiner  
Art Unit 3762

2/20/4

GRE

February 20, 2004